

**CONTACT LENS PACKAGES CONTAINING ADDITIVES
RELATED APPLICATIONS**

This application is a non-provisional filing of a provisional application, U.S. Pat. App. No.60/436,109, filed on December 23, 2002.

5

FIELD OF THE INVENTION

This invention related to packages for storing contact lenses as well as methods of using and preparing these packages.

BACKGROUND

10 Contact lenses have been used commercially to improve vision since the 1950s. At first contact lenses were made of hard materials, which were relatively easy to handle and package for use, but were uncomfortable for many patients. Later developments, gave rise to softer more comfortable lenses made of hydrophobic hydrogels, particularly silicone hydrogels. These lenses are very pliable, but due to this texture and their chemical composition,
15 they present a number of problems with packaging.

Most contact lenses are packaged in individual blister packages having a bowl portion and a foil top, where the bowl portion is made from a hydrophobic material such as polypropylene. See U.S. Patent Nos. 4,691,820; 5,054,610; 5,337,888; 5,375,698; 5,409,104; 5,467,868;
20 5,515,964; 5,609,246; 5,695,049; 5,697,495; 5,704,468; 5,711,416; 5,722,536; 5,573,108; 5,823,327; 5,704,468; 5,983,608; 6,029,808; 6,044,966; and 6,401,915 for examples of such packaging, all of which are hereby incorporated by reference in their entirety. While polypropylene is resilient enough to withstand the sterilization steps of contact lens
25 manufacture, this material has an affinity for contact lenses made of silicone hydrogels. When silicone hydrogels are packaged in polypropylene bowls, the lenses stick to the bowl and cannot be removed from the package without damaging the pliable lenses. Therefore is a need to prepare a contact lens package that has resilient properties, but does not stick to the final product. It
30 is this need that is met by the following invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates the data for Lens A in different packages

Figure 2 illustrates the data for Lens B in different packages

Figure 3 illustrates the data for Lens C in different packages

DETAILED DESCRIPTION OF THE INVENTION

This invention includes a package for storing medical devices in a
5 solution comprising, consisting essentially of, or consisting of,
a molded base wherein the molded base comprises an additive, provided that
the medical device is not a contact lens consisting of acqualfilcon A coated
with polyHema.

As used herein a "medical device" is any device that is stored or
10 packaged in a solution and is used to treat a human disease. Examples of
medical devices include but are not limited to ophthalmic devices that reside
in or on the eye. Ophthalmic devices includes but are not limited to soft
contact lenses, intraocular lenses, overlay lenses, ocular inserts, and optical
inserts. These devices can provide optical correction or may be cosmetic.
15 The preferred medical devices of the invention are soft contact lenses made
from silicone elastomers or hydrogels, which include but are not limited to
silicone hydrogels, and fluorohydrogels. Soft contact lens formulations are
disclosed in U.S. Pat. App. No. 60/318,536, entitled Biomedical Devices
Containing Internal wetting Agents," filed on September 10, 2001 and its non-
20 provisional counterpart of the same title, filed on September 6, 2002, US
Patent No. 5,710,302, WO 9421698, EP 406161, JP 2000016905, U.S. Pat.
No. 5,998,498, US Pat. App. No. 09/532,943, U.S. Patent No. 6,087,415,
U.S. Pat. No. 5,760,100, U.S. Pat. No. 5,776, 999, U.S. Pat. No. 5,789,461,
U.S. Pat. No. 5,849,811, and U.S. Pat. No. 5,965,631. The foregoing
25 references are hereby incorporated by reference in their entirety. The
particularly preferred medical devices of the invention are soft contact lenses
made from etafilcon A, genfilcon A, lenefilcon A, polymacon, balafilcon A,
lotrafilcon A. and silicone hydrogels as prepared in U.S. Pat. No. 5,998,498,
U.S. Pat. App. No. 09/532,943, a continuation-in-part of US Pat App. No.
30 09/532,943, filed on August 30, 2000, U.S. Patent No. 6,087,415, U.S. Pat.
No. 5,760,100, U.S. Pat. No. 5,776, 999, U.S. Pat. No. 5,789,461, U.S. Pat.
No. 5,849,811, and U.S. Pat. No. 5,965,631. These patents as well as all

other patent disclosed in this application are hereby incorporated by reference in their entirety. The more particularly preferred medical devices of the invention are soft contact lenses, balafilcon A, lotrafilcon A, galyfilcon A, senofilcon A, or those made as described in U.S. Pat. App. No. 60/318,536, entitled Biomedical Devices Containing Internal wetting Agents," filed on September 10, 2001 and its non-provisional counterpart of the same title, filed on September 6, 2002. The most particularly preferred medical devices are soft contact lenses made from either galyfilcon A or senofilcon A.

The term "molded base" refers to any polymer, rubber, or plastic that can be formed into a receptacle for medical devices, where the size and shape of the base are determined by the device and other considerations known those who are skilled in the art of making or designing molded bases. For example molded bases may be individual blister packages, secondary packages, or hydrating trays. The molded base may be prepared from any number of materials provided that those materials are compatible with the chemical and physical properties of the device. Examples of suitable materials include but are not limited to polypropylene, polyethylene, nylons, olefin co-polymers, acrylics, rubbers, urethanes, polycarbonates, or fluorocarbons. The preferred materials are metallocenes polymers and co-polymers made of polypropylene, polyethylene, having a melt flow range of about 15 g/10 minutes to about 44 g/10 minutes as determined by ASTM D-1238. With respect to the shape of the molded base, examples of suitably shaped bases are disclosed in the following patents which are hereby incorporated by reference in their entirety, U.S. Patent Nos. D 458,023; 4,691,820; 5,054,610; 5,337,888; 5,375,698; 5,409,104; 5,467,868; 5,515,964; 5,609,246; 5,695,049; 5,697,495; 5,704,468; 5,711,416; 5,722,536; 5,573,108; 5,823,327; 5,704,468; 5,983,608; 6,029,808; 6,044,966; and 6,401,915. As in the cited references, the molded based is sealed about the cavity that encloses the contact lens. Flexible cover sheets can be made from can be an adhesive laminate of an aluminum foil and a polypropylene film or any other extruded or co-extruded film that can be sealed to the top surface of the flange in order to form a hermetic seal for the medical device and the solution.

VTN 632 USNP

Further, the base can be formed by any of a number of known methods which include but are not limited to injection molding, transfer molding, skin packaging, blow molding, coinjection molding, film extrusion, or film co-extrusion.

- 5 As used herein the term "additive" refers to a substance that is added to the polymer, rubber, or plastic prior to forming the molded base, where the material inhibits sticking, adherence, or adhesion of the medical device to the molded base. The additive is mixed with the remainder of the molded base material and amount of additive present by weight percentage based on the
- 10 total weight of the molded base material is greater than about 0.25 to about 10 weight percent, preferably greater than about 0.25 to about 5 weight percent, most preferably about 0.25 to about 3 weight percent. The preferred additives are glycerol monostearate (2%), polyvinylpyrrolidone (1% to 5%), polyvinylpyrrolidone/maleic anhydride (1/1% to 5/5%), and succinic acid (5%).
- 15 Polyvinylpyrrolidinone has a variety of molecular weight ranges (as indicated by the KD#) and consistencies (flake, powdered/micronized). When PVP KD90 is used as an additive, it is preferred that it is powered/micronized.

- The term "solution" refers to any liquid medium in which a medical device is stored. The preferred solutions are aqueous solutions contain
- 20 physiological buffers. The particularly preferred solution is saline solution.

- For example, if the medical device is a contact lens, it is preferred that the molded base is transparent to the degree necessary to permit visual inspection, UV sterilization or both. The preferred additives are glycerol monostearate present at about 2 weight percent, succinic acid present at
- 25 about 5 weight percent, PVP KD90 present at about 1-5 weight percent, PVP/maleic anhydride present at about 1/1 to about 5/5 weight percent. If the inner surface of the medical device has a roughness of about 0.2 μm to about 4.5 μm , the preferred additives are maleic anhydride or PVP/maleic anhydride, most preferably maleic anhydride.

- 30 Further, the invention includes a method of reducing the adherence of a medical device to its packaging, comprising, consisting essentially of, or consisting of, storing said medical device in a solution in a package

comprising, consisting essentially of, or consisting of, a molded base wherein said molded base comprises an additive, provided that the medical device is not a contact lens consisting of acqualfilcon A coated with polyHema. The terms molded base, medical device, solution and additive all have their
5 aforementioned meanings and preferred ranges.

When soft contact lenses are prepared, the lenses cured to a hard disc and subsequently hydrated with water to give the non-sterilized final product. During this hydration step, soft contact lenses often stick to the surface of the hydration chamber and it would useful to find a method of hydrating soft
10 contact lenses which alleviates this problem.

To solve this problem, the invention includes a method of hydrating a contact lens comprising, consisting essentially of, or consisting of hydrating said lens in a molded base wherein said molded base comprises an additive. The terms molded base, medical device, solution and additive all have their
15 aforementioned meanings. The preferred values for the medical device, the solution and the additive are as listed above. The preferred molded base is a square or a rectangle.

Other have tried to address the problem of a medical device adhering to its packaging. For example U.S. Pat App. No. 09/942,347, entitled
20 "Textured Contact Lens Package," filed on August 29, 2001 and U.S. Pat. App. No. 10/183,133, entitled "Contact Lens Packages," filed on June 26, 2002 disclose solutions to this problem. The disclosure of these applications are hereby incorporated by reference in their entirety. Even though those methods address this problem, it is contemplated by the inventors of this
25 patent application that the additives of this invention may be incorporated into the packaging of each of the cited references.

In order to illustrate the invention the following examples are included. These examples do not limit the invention. They are meant only to suggest a method of practicing the invention. Those knowledgeable in contact lenses as
30 well as other specialties may find other methods of practicing the invention. However, those methods are deemed to be within the scope of this invention.

EXAMPLES

VTN 632 USNP

The following abbreviations are used below

	Ampacet 40604	fatty acid amide
	ATOFINA 3924CWZ	Finacene Nucleated polypropylene having a melt flow of 55g/10 minutes, ASTM D1238. This material contains an antistat and a lubricant
5	Atmer 163	fatty alkyl diethanolamine Reg. No.107043-84-5
	Dow Siloxane MB50-321	a silicone dispersion
	Epolene E43-Wax,	maleic anhydride produced by Eastman Chemical
	Erucamide	fatty acid amide Registry No. 112-84-5
10	Exxon 1605	Exxon Achieve, PP1605, a metallocene polypropylene having a melt flow of 32 g/10 minutes, ASTM D-1238 (L)
	Exxon 1654	Exxon Achieve, PP1654, a metallocene isotactic polypropylene having a melt flow of 16 g/10 minutes, ASTM D-1238 (L)
15	Fina EOD-001	Finacene, a metallocene and isotactic polypropylene having a melt flow of 16g/10 minutes, ASTM D1238
	Flura	Registry No.7681-49-4
20	Kemamide	fatty acid amide
	Licowax	fatty acid amide
	Mica	Registry No. 12001-26-2
	Nurcrel 535 & 932	ethylene-methacrylic acid co-polymer resin
		Registry No. 25053-53-6
25	Oleamide	fatty acid amide Registry No. 301-02-0
	polyHema	poly hydroxy ethylmethacrylate having a molecular weight of greater than 1MM Dalton
	mPDMS	800-1000 MW monomethacryloxypropyl terminated polydimethylsiloxane
30	Pluronic	polyoxypropylene-polyoxyethylene block co-polymer Registry No.106392-12-5

VTN 632 USNP

	PVP	poly vinyl pyrrolidinone, wherein KD# refers to different known molecular weight distributions of poly vinyl pyrrolidinone
	Simma 2	3-methacryloxy-2-hydroxypropyloxy)propylbis (trimethylsiloxy)methylsilane
5	Super-Floss anti block	slip/anti blocking agent, Registry No. 61790-53-2
	Tetronic	alkyoxylated amine 110617-70-4
	Zeospheres anti-block	slip/anti blocking agent
	Lens Preparations	
10	Lens A	Acquafilcon A lenses coated with polyhema having a molecular weight of about 1,000,000. See U.S. Pat App. No. 09/957,299, entitled "Soft Contact Lenses," filed on September 20, 2001, Example 27. The coating method is disclosed in U.S. Pat. App. No. 09/921,192, entitled "Method for
15		Correcting Articles by Mold Transfer," filed on August 2, 2001.
	Lens B	Contact lenses prepared as described in U.S. Pat. App. No. 60/318,536, entitled Biomedical Devices
20		Containing Internal wetting Agents," filed on September 10, 2001 and its non-provisional counterpart of the same title, filed on September 6, 2002, containing by weight percent 30% Simma 2,
		19% mPDMS, 31% DMA, 6% PVP (MW 360,000),
25		0.8%EDGMA, 0.23% CGI81, 1.5% Norbloc, 11% PVP (MW 2,500), 0.02% Blue Hema, 0-2 ac
		PDMS, 29% t-amyl alcohol.
	Lens C	Contact lenses prepared as described in U.S. Pat. App. No. 60/318,536, entitled Biomedical Devices
30		Containing Internal wetting Agents," filed on September 10, 2001 and its non-provisional

counterpart of the same title, filed on September 6, 2002, containing by weight percent 28% Simma 2, 31% mPDMS, 23.5% DMA, 7% PVP (MW 360,000), 1.5% TEDGMA, 0.98% CGI 1850, 2.0% Norbloc, 6 HEMA, 0.02% Blue Hema.

Example 1

Preparation of Packages with Different Additives

Additives (identity and amounts listed in Table 1) were mixed with polypropylene (listed below). The material was injection molded to form the base portion of a contact lens package. The configuration of the package is as illustrated in Figure 1 of U.S. Pat No. 5,467,868 which is hereby incorporated by reference.

Contact lenses made from aquafilcon A coated with polyhema, a silicone hydrogel, were added to individual polypropylene blister packs having different additives containing 950 μ L of saline solution and then the blister pack was heat sealed with an flexible cover. Lenses were visually evaluated for adhesion to the package after sterilization. The flexible cover sheet was removed and the molded base is rotated or jiggled without spilling the saline solution while a contact lens is observed to determine if it is adhered to the inner surface of the molded base. Lenses that do not adhere are free floating and pass the test. If the lenses adhere to the molded base in any manner they fail the test. The additive, its weight percentage, the number of lenses that stuck to the package, and number of lenses that were free floating are displayed in Table 1. This example illustrates that glycerol monostearate is a superior additive.

TABLE 1

	<u>Polypropylene</u>	<u>Additive</u>	<u># tested</u>	<u># stuck</u>
	Exxon 1605	none	12	12
30	Exxon 1605	calcium stearate	36	36
	Exxon 1605	2% glycerol monostearate	36	3
	Exxon 1654	2% glycerol monostearate	84	2

VTN 632 USNP

	Exxon 1654	none	12	12
	Exxon Exxelor P1020	none	12	12
	Fina EOD-0011	none	12	12
	Fina EOD-0011	1% zinc stearate	12	12
5	Fina EOD-0011	3% zinc stearate	12	12
	FINA 3924CW@	antistat	36	36

Example 2

Consumer Test

10 Packages containing 2% weight percent GMS and Exxon 1605 were prepared using the method of Example 1. Contact lenses of types A, B, and C were added to individual blister packages along with 950 μ L of saline solution. The filed packages were heat sealed with flexible covers and sterilized. The packaged lenses were submitted to consumers. The
15 consumers opened the packages and evaluated the lenses for ease of removal of the lens from the package using the following criteria and grading system

- 1-very easy removal-Lens comes out without any problems
- 2-easy removal-a couple of attempts to remove the lenses, but overall
20 there were no real problems in removal
- 3-moderate removal- several tries before lens comes out, neither pleased or displeased
- 4-difficult removal-many tries to remove with finger or nail-removal is frustrating
- 25 5-very difficult removal-many tries to remove with a finger or nail, lens damage upon removal- very unacceptable

Figure 1 illustrates the testing results for a comparison of Lens A in a polypropylene package (control), Lens A in a package containing 2.0% GMS where the package has an average surface roughness (Ra) of about 2.0 μ m,
30 and Len A in a package containing 2.0% GMS. This figure shows that the roughened package containing GMS has the highest consumer rating.

VTN 632 USNP

Figure 2 illustrates the testing results for a comparison of Lens B in a polypropylene package (control), Lens B in a package containing 2.0% GMS where the package has an average surface roughness (Ra) of about 2.0 μm , and Len B in a package containing 2.0% GMS. This figure shows that the
5 package containing 2.0 %GMS has the highest consumer rating.

Figure 3 illustrates the testing results for a comparison of Lens C in a polypropylene package (control), Lens C in a package containing 2.0% GMS where the package has an average surface roughness (Ra) of about 2.0 μm ,
10 and Len C in a package containing 2.% GMS. This figure shows that the package containing 2.0 %GMS has the highest consumer rating.

Example 3

Preparation of Packages With Different Additives

The testing methods and preparations of Example 1 were repeated
15 with different additives and lens types as per Table 2. If "(UP)" appears in an entry, that bowl of the blister is shaped as in U.S. Pat. No. D 458,023. When the term "Rough Bowl" appears, the inside surface of the bowl is roughened to an Ra of 0.5mm to 0.8mm.

	Base Resin	Lens Type	Table 2		Additive
			Tested	Stuck	
20	Exxon 1605 PP	Lens B	15	13	Calcium stearate (2%)
	Exxon 1605 PP	Lens B	120	0	GMS (2%)
	Exxon 1605 PP	Lens C	30	0	GMS (2%)
	Exxon 1605 PP	Lens B	15	12	Dow Siloxane MB50-321 (10%)
25	Exxon 1605 PP	Lens B	15	13	Dow Siloxane MB50-321 (5%)
	Exxon 1605 PP	Lens B	57	50	Ampacet 40604 99.5/.5 Erucamide
	Ampacet 40604 PP	Lens B	15	15	Erucamide (5%)
	Exxon 1605 PP	Lens B	15	15	Kemamide (Erucamide) (5%)
	Exxon 1605 PP	Lens B	15	12	Superfloss anti-bock (2%)
30	Exxon 1605 PP	Lens B	15	15	Zeospheres anti-block (2%)
	Exxon 1605 PP	Lens B	15	14	Superfloss anti-bock (2%) Oleamide (.2%)
	Exxon 1605 PP	Lens B	14	13	Superfloss anti-bock (.2%) Oleamide (.2%)
35	Exxon 1605 PP	Lens B	15	15	Talc (5%)
	Exxon 1605 PP	Lens B	15	13	Calcium carbonate (5%)
	Exxon 1605 PP	Lens B	15	14	Zinc stearate (5% hand blend)
	Exxon 1605 PP	Lens B	15	15	Zinc stearate (5% machine blend)
	Exxon 1605 PP	Lens B	15	14	ATP (Vitamin E) (5%)
40	Exxon 1605 PP	Lens B	15	13	Licowax (1%)
	Exxon 1605 PP	Lens B	15	14	Polyethyleneglycol monolaurate (5%)
	Exxon 1605 PP	Lens B	15	15	Mica (5%)

VTN 632 USNP

5	Exxon 1605 PP	Lens B	175	8	Succinic Acid (5%)
	Exxon 1605 PP	Lens B	15	13	Succinic Anhydride (5%)
	Exxon 1605 PP	Lens B	118	22	Epolene E-43 (20% machine blend)
	Exxon 1605 PP	Lens B	100	92	Epolene E-43 (20% machine blend)
	Exxon 1605 PP	Lens B	127	52	Epolene E-43 (10% hand blend)
10	Exxon 1605 PP	Lens B	130	16	Epolene E-43 (10% machine blend)
	Exxon 1605 PP	Lens C	15	6	Epolene E-43 (10% machine blend)
	Exxon 1605 PP	Lens B	30	22	Epolene E-43 (5% machine blend)
	Exxon 1605 PP	Lens C	15	3	Epolene E-43 (5% machine blend)
	Exxon 1605 PP	Lens B	15	15	Atmer 163 (1%)
15	Exxon 1605 PP	Lens B	15	10	MC (5%)
	Exxon 1605 PP	Lens B	30	2	Boric Acid (5% hand blend)
	Exxon 1605 PP	Lens B	215	3	Boric Acid (5% machine blend)
	Exxon 1605 PP	Lens C	15	0	Boric Acid (5% machine blend)
	Exxon 1605 PP	Lens B	15	13	Boric Acid (3% hand blend)
20	Exxon 1605 PP	Lens B	15	15	Boric Acid (2% hand blend)
	Exxon 1605 PP	Lens B	150	4	Epolene E-43 (10% machine blend)
	Exxon 1605 PP	Lens B	50	9	Epolene E-43 (10% machine blend)
	Exxon 1605 PP	Lens B	50	15	Epolene E-43 (10% machine blend)
	Exxon 1605 PP	Lens B	50	35	Epolene E-43 (10% machine blend)
25	Exxon 1605 PP	Lens B	255	6	PVP K90 (5.0%)
	Exxon 1605 PP	Lens B	98	31	PVP K90 (2.5%)
	Exxon 1605 PP	Lens B	98	49	PVP K90 (1.25%)
	Exxon 1605 PP	Lens B	20	6	PVP K90 (1.0%)
	Exxon 1605 PP	Lens B	20	10	PVP K90 (.75%)
30	Exxon 1605 PP	Lens B	20	17	PVP K90 (.5%)
	Exxon 1605 PP	Lens C	248	5	PVP K90 (5.0%)
	Exxon 1605 PP	Lens C	39	0	PVP K90 (10%) Blended down to 5%
	Exxon 1605 PP	Lens C	135	42	PVP K90 (2.5%)
	Exxon 1605 PP	Lens C	135	54	PVP K90 (1.25%)
35	Exxon 1605 PP	Lens C	70	42	PVP K90 (1.0%)
	Exxon 1605 PP	Lens C	70	50	PVP K90 (.75%)
	Exxon 1605 PP	Lens C	70	60	PVP K90 (.5%)
	Exxon 1605 PP	Lens B	15	14	Nucrel 535 - 10.5% acid comonomer (2%)
	Exxon 1605 PP (3%)	Lens B	15	15	Nucrel 925 - 15% acid comonomer
40	Exxon 1605 PP (2%)	Lens C	15	14	Nucrel 535 - 10.5% acid comonomer
	Exxon 1605 PP (3%)	Lens C	15	14	Nucrel 925 - 15% acid comonomer
	Exxon 1605 PP	Lens B	15	15	2% XNAP with Pluronic
	Exxon 1605 PP	Lens C	15	14	2% XNAP with Pluronic
	Exxon 1605 PP	Lens B	15	15	Pluronic 1%
45	Exxon 1605 PP	Lens C	15	15	Pluronic 1%
	Exxon 1605 PP	Lens B	15	11	1% Tetronic
	Exxon 1605 PP	Lens C	15	15	1% Tetronic
	Exxon 1605 PP	Lens B	15	15	1% Flura
	Exxon 1605 PP	Lens C	15	15	1% Flura
50	Exxon 1605 PP	Lens B	30	23	2% Pluronic
	Exxon 1605 PP	Lens C	30	16	2% Pluronic
	Exxon 1605 PP	Lens C	77	0	PVP K90 (5%) + Epolene E43 (5%)
	Exxon 1605 PP	Lens B	50	0	PVP K90 (5%) + Epolene E43 (5%)
	Exxon 1605 PP	Lens C	62	0	PVP K90 (5%) + Epolene E43 (1.5%)
55	Exxon 1605 PP	Lens B	50	0	PVP K90 (5%) + Epolene E43 (1.5%)

VTN 632 USNP

	Exxon 1605 PP	Lens C	65	0	PVP K90 (2.5%) + Epolene E43 (1.25%)
	Exxon 1605 PP	Lens B	50	0	PVP K90 (2.5%) + Epolene E43 (1.25%)
5	Exxon 1605 PP	Lens C	115	10	PVP K90 (1%) + Epolene E43 (1%)
	Exxon 1605 PP	Lens B	100	11	PVP K90 (1%) + Epolene E43 (1%)
	Exxon 1605 PP	Lens C	30	0	PVP K29/31 (5%)
	Exxon 1605 PP	Lens C	30	0	PVP K60 (5%)
	Exxon 1605 PP	Lens B	50	0	PVP K90 (1%) + Rough Bowl (UP)
10	Exxon 1605 PP	Lens C	50	0	PVP K90 (1%) + Rough Bowl (UP)
	Exxon 1605 PP	Lens B	170	0	Epolene E43 (1%) + Rough Bowl
	Exxon 1605 PP	Lens C	200	0	Epolene E43 (1%) + Rough Bowl